MedImmune, Inc.

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November 17, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Federal Register Vol. 64 No. 160 / Thursday August 19, 1999 page 45383.
Plasma derivatives and Other Blood-Derived Products; Requirements for Tracking and Notification.

MedImmune wishes submit the following comments regarding under the Advanced Notice of Proposed Rulemaking.

1. Requiring all end users of blood products to register with the manufacturer could lead to possible violations patient confidentiality if the definition of the end user is the patient. Utilization of an independent third party to administer the database could still pose the potential for violations of confidentiality if the information were to inadvertently release to the general public.

2. Specialty hyperimmune globulins such as Cytomegalovirus Immune Globulin Intravenous (Human) are not generally prescribed for home use and are not generally self-administerd. We believe these products should be excluded from any requirement for a tracking system.

3. Simply tracking purchasers of a blood product would not be effective in a recall situation unless the lot number of the product prescribed was known. The hospital, pharmacy or home healthcare company that provides the blood product to the patient should be required to record the lot numbers prescribed. However currently there is no legislation in place to require this.

4. Since hospitals, pharmacies and home healthcare organizations and health clinics deal with blood products at the patient level, legislation should be enacted to require hospitals, pharmacies, home healthcare organizations and health clinics to track patients who receive blood products and the lot numbers they receive.

5. Record keeping for tracking all patients who receive blood products would be extremely burdensome and costly to the manufacture. Creating and maintaining a database is costly. Obtaining data would be complicated and difficult to obtain due to the network of distribution of the product. The network involves large distributors, small distributors and hospitals, home healthcare companies and health clinics.

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6. If patient tracking and recall notification becomes mandatory then notification should be limited to adverse events where there is a potential for transmission of infectious disease. Mandatory notification should be limited to two documented attempts to notify patients of the recall.

Sincerely,

Bogdan Dziurzynski
Senior Vice President
Regulatory Affairs and Quality Assurance

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